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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,386	12/27/2004	Marie-Noelle Horcajada	P70350US0	6940

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

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09/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,386	HORCAJADA ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 13-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on June 16, 2009.

Claim(s) 2-11 and 13-22 are examined herein.

Response to Arguments

In view of Applicant's arguments, the 103(a) rejection of claims 2-8, 10-11, and 13-22 as being unpatentable over Wenzel et al. (EP 1127572A2) of record as evidenced by (Katori, et al., *Inflammatory Research*, 2000) of record and Hofbauer et al (*Journal of Molecular Medicine*, 2001) of record is hereby withdrawn.

In view of Applicant's arguments, the 103(a) rejection of claim 9 as being unpatentable over Wenzel et al. (EP 1127572A2) as evidenced by (Katori, et al., *Inflammatory Research*, 2000) and Hofbauer et al (*Journal of Molecular Medicine*, 2001) as applied to claims 2-8, 10-11, and 13-22 above in view of Barnes et al. (US Patent No. 5,506,211) is hereby withdrawn.

A new 103(a) rejection is set forth on record in the non-final office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-8, 10-11, and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bok et al. (WO 98/16220) in view of Kim (WO 98/16220) in view further view of Bok (US 2001/0014669 A1).

Bok (WO) teaches pharmaceutical compositions for inhibiting the HMG-CoA reductase activity in mammals, which comprises hesperidin or hesperitin as an active ingredient, in combination with pharmaceutically acceptable excipients, carriers or diluents (page 3 lines 24-28).

Bok (WO) teaches that hesperidin and hesperitin may be extracted from the peel of citrus or synthesized (page 3, lines 29-30).

Bok (WO) further teaches that the hesperidin and hesperitin can be incorporated in foods and beverages for the purpose of inhibiting the HMG-CoA reductase activity (page 5, lines 17-23).

Additionally, Bok (WO) teaches that the pharmaceutical formulations can be administered via various routes including oral, transdermal, subcutaneous, intravenous and intramuscular introduction. In case of human, a typical daily dose of hesperidin or hesperitin may range from about 0.5 to 300 mg/kg body weight, preferably 5 to 30 mg/kg body weight, and can be administered in a single dose or in divided doses (page 5, lines 3-8).

Bok (WO) does not teach hesperidin as a method for stimulating bone formation and/or inhibiting bone resorption and the diseases associated therewith.

Kim teaches a therapeutic agent for osteoporosis comprising an active ingredient of quercetin derivatives which effectively stimulate osteoblast proliferation and inhibit osteoclast proliferation. The quercetin derivatives of the invention can be practically applied for the treatment and prevention of osteoporosis, since they effectively inhibit osteoclast proliferation and stimulate osteoblast proliferation more than conventional therapeutic agents for osteoporosis (page 29, lines 4-13).

Bok (US) teaches a method of inhibiting the activity of HMG CoA reductase in mammals with the administration of quercetin ([0025]; claim 1).

Bok (US) teaches that quercetin can be incorporated in foods or beverages for the purpose of treating or preventing hyperlipidemia, arteriosclerosis, angina pectoris, stroke, and hepatic diseases. The foods or beverages may include meats; juices such

as a vegetable juice (e.g., carrot juice and tomato juice) and a fruit juice (e.g., orange juice, grape juice, pineapple juice, apple juice and banana juice); chocolates; snacks; confectionery; pizza; food products made from cereal flour such as breads, cakes, crackers, cookies, biscuits, noodles and the likes; gums; dairy products such as milk, cheese, yogurt and ice creams; soups; broths; pastes, ketchups and sauces; teas; alcoholic beverages; carbonated beverages; vitamin complexes; and various health foods [0030].

Bok (US) teaches that is quercetin is a bioflavanoid that can be found in citrus fruits such as grapefruit and lemon (page 1, table 1). Similarly, table 1 shows that hesperidin and hesperidin are also isolated from the same sources.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed hesperidin, which is an HMG CoA reductase inhibitor as taught by Bok (WO), as a treatment agent for bone disorders, namely osteoporosis. One would be motivated to employ hesperidin for such therapeutic applications because Kim teaches that quercetin, a bioflavanoid differing from hesperidin by a hydroxyl moiety, is employed as a therapeutic agent for osteoporosis. The nexus between the two compounds is brought together by Bok (US) which teaches that quercetin is also an HMG CoA reductase inhibitor. Additionally, as is well known in the art and documented by Bok (US), quercetin and hesperidin are readily found in citrus fruit. Thus, because both hesperidin and quercetin are bioflavanoids and found from the same natural sources and further are found to be HMG CoA reductase inhibitors, then one would expect, with a reasonable degree of success that if quercetin is an

agent possessing the therapeutic potential of treating osteoporosis, then it would be likely that hesperidin would also be likely to have such potential and would be equally successful in treating such bone disorders, in the absence of unexpected results.

Furthermore, the incorporation of hesperidin in the various food and drink products can be targeted to different age groups, i.e. young or old, human or animal, depending on the nature of the food product.

Conclusion

Claims 2-11 and 13-22 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617